

### **REMARKS**

After this Amendment, claims 1-5, 23-34 and 40-44 are now pending in the application. Claim 1 has been amended, new claims 40-44 have been added, and claims 35-39 are cancelled without prejudice or disclaimer by this Amendment. Reconsideration of the previously rejected claims and favorable action is requested in light of the above amendments and the following remarks.

#### **Ahmadi in view of Forsell**

In the present Office Action, claims 1-5 and 23-34 are rejected under 35 U.S.C. § 103(a) as being anticipated by U.S. Patent No. 4,602,911 to Ahmadi et al. (hereafter "Ahmadi") in view of U.S. Patent No. 6,067,991 to Forsell (hereafter "Forsell"). Insofar as this ground for rejection applies to the present claims, Applicants respectfully traverse.

As noted in Applicants' prior remarks, Ahmadi discusses an adjustable annular device which engages with a tool. Forsell discloses a food intake restriction device for surgical application in the abdomen of a patient. The device includes an elongated non-inflatable restriction member, a forming device for forming the elongated restriction member into at least a substantially closed loop *around the stomach or the esophagus* to define a restriction opening, and a post-operation non-invasive adjustment device for mechanically adjusting the restriction member in the loop to change the size of the restriction opening.

To establish a prima facie case of obviousness, three criteria must be met. First, there must be some reason to modify the reference or to combine the reference teachings. Second, there must be some expectation of success. Third, the prior art references must disclose or suggest all of the claimed features. See MPEP 2143 and the May 3, 2007 letter from the PTO Deputy Commissioner for Patent Operations regarding *KSR Int'l Co. v. Teleflex, Inc.* Applicant respectfully submits that this criterion has not been met for Ahmadi in view of Forsell as applied to claims 1-5 and 23-34.

Claim 1 presently recites, in part, "introducing an adjustable implant device adjacent to an internal surface near said anatomic orifice or lumen, said implant device substantially defining a plane ... wherein, when operably engaged, at least the distal portion of said adjustment tool is disposed in a non-planar orientation with respect to said plane defined by said implant device."

The device and adjustment mechanism of Ahmadi provides a specific arrangement to meet the need for “accurate and troublefree adjustment without danger of jamming of the adjustment device” (Ahmadi, co. 1, lines 38-39). Ahmadi’s solution includes use of a coiled band with a toothed edge to engage a screw rotatably held for being turned by an adjusting tool (see Ahmadi, col. 4, lines 12-22). Ahmadi does not teach or suggest an adjustment mechanism suitable for a non-planar orientation (or any other alternate arrangement for the adjustment mechanism), since, predictably, reorientation of the Ahmadi mechanism would eliminate the orientation that provides the “accurate and troublefree adjustment without danger of jamming” that was intended. The fact that a prior art device could be modified so as to produce the claimed device is not a basis for an obviousness rejection unless the prior art suggested the desirability of such a modification. See *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

Forsell does not supply the deficiency of Ahmadi, in that Forsell also fails to disclose an adjustment tool disposed in a *non-planar orientation* with respect to said plane defined by the implant device. In fact, as shown in Fig. 1 and 3 of Forsell, the adjustment tool (post-operation mechanical adjustment device 12) of Forsell is disposed in exactly a planar orientation with respect to said plane defined by the implant device. Furthermore, because of the comparative lack of space constraints around the stomach or esophagus, there is no suggestion in Forsell to adapt the device to accommodate a non-planar orientation of the tool. Thus, neither Ahmadi or Forsell alone or in combination disclose or suggest all the elements of claim 1.

As an additional distinction, Forsell’s disclosure of an adjustment device provides for adjustment of a band around the outside of the stomach or esophagus. Thus, Forsell does not disclose an adjustable implantable device “adjacent to an internal surface near said orifice or lumen,” as recited in claim 1. Because Forsell’s device wraps around an exterior surface, access to the adjustment mechanism and the dimensional proportions of both the adjustment tool and the adjustment mechanism are much less constricted than they would be for an attachment on the internal surface of an orifice or lumen, such as disclosed in Ahmadi. The device of Forsell is therefore not suitable in combination with Ahmadi to achieve adjustment “adjacent to an internal surface near said orifice or lumen” as claimed. Thus, Applicants respectfully submit that claim 1 of the present invention is not rendered obvious by Ahmadi in view of Forsell.

Claims 2-5 and 23-34 depend directly or indirectly from claim 1 and incorporate all the

features therein. Thus, claims 2-5 and 23-34 are allowable over the cited references for at least the same reasons that claim 1 is allowable. In light of the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1-5 and 23-34 under 35 U.S.C. § 103(a).

Claims 40-44 are newly submitted. Independent claim 40 and the following dependent claims are directed to the same invention of the preceding claims and include several common limitations. Applicants submit the feature of recited in claim 40 of “inserting the adjustment tool axially along at least a portion of the anatomic orifice or lumen to operably engage said docking mechanism” is not taught or suggested by Ahmadi and/or Forsell. Review on the merits is respectfully requested.

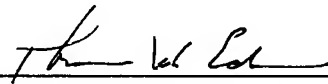
**CONCLUSION**

In view of the foregoing, Applicants submit that this application is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that the prosecution of this case might be advanced by discussing the application with Applicants' representative, in person, or over the telephone, Applicants' representatives would welcome the opportunity to do so.

EXCEPT for fees payable under 37 CFR §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit, any overpayment to deposit account No. 50-1349. This paragraph is intended to be a constructive petition for extension of time in accordance with 37 CFR §1.136(a)(3).

Respectfully submitted,

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